

Application No. 10/035,861
Amdt. Dated January 29, 2005
Reply to Office Action of September 30, 2004

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REMARKS/ARGUMENTS

1. Remarks on the Amendment

Claims 26-29, withdrawn in response to the restriction requirement, have been canceled.

Claims 1, 14 and 24 have been amended to more specifically reflect Applicant's claimed method of detection of multiple test materials by a sequential process. The antecedent basis of the amendment can be found in the amended claims as filed and in Figs. 6-12 of the Specification as filed. Applicant respectfully submits that no matter is added by the amendment.

2. Response to the Double Patenting Rejections

(1) Claims 1, 2, 6 and 14-15 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 5-6 of US 6,174,733.

(2) Claims 3-5 and 16-17 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 5-6 of US 6,174,733 in view of Lee et al (US 5,672,475).

(3) Claims 1, 2, 6 and 14-15 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 14-22 of US 6,337,214.

(4) Claims 3-5 and 16-17 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 14-22 of US 6,337,214 733 in view of Lee et al (US 5,672,475).

These rejections are respectfully traversed.

Obviousness-type double patenting is a judicial creation designed to preclude improper timewise extension of the patent rights by proscribing the issuance of

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claims in a second patent that are not "patently distinct" from the claims of a first patent. In *re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991).

Thus the principal inquiry is "whether the claimed invention in the application for the second patent would have been obvious from the subject matter of the claims in the first patent, in light of the prior art." In *re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Determination of obviousness-type double patenting essentially involves the determination of unobviousness under 35 USC § 103, except that the first patent disclosure is not applicable as "prior art." In *re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Importantly, there must be some clear evidence to establish why the invention's variation in the second application would have been obvious, with that evidence properly qualifiable as "prior art."

In the present application, Claims 1, 2, 6, 14 and 15 are patentably distinct over Claims 5 and 6 of US patent No 6,174,733 and further patentably distinct over Claims 14-22 of US patent No 6,337,214.

More specifically, Claims 1, 2, 6, 14 and 15 of the present claimed invention relate to a method of detecting multiple test materials on the same test snare using a sequential process by adding the probes at different times, triggering and detecting the signals from the labeled test materials at different times.

Neither Claims 5 and 6 of US patent No 6,174,733, nor Claims 14-22 of US patent No 6,337,214 teach a method of detecting multiple test materials on the same test snare using a sequential process by adding the probes at different times, triggering and detecting the signals from the labeled test materials at different times. The method defined by independent Claims 1 and 14 of the instant application are illustrated step by step in Figs. 6-12 of the instant specification, and such process was not present in the US patent Nos. 6,174,733 and 6,337,214

Accordingly, Applicants request withdrawal of the rejection of Claims 1, 2, 6, 14 and 15 under the judicially created doctrine of obviousness-type double patenting.

With regard to Claims 3-5 and 16-17, since they are dependent upon

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independent Claims 1 and 14, under the principles of 35 U.S.C. §112, 4th paragraph, all of the limitations of each independent claim are recited in its respective dependent claims. As described above, the independent Claims 1 and 14 of the present claimed invention are patentably distinct over Claims 5 and 6 of US patent No 6,174,733 and further patentably distinct over Claims 14-22 of US patent No 6,337,214, as such Claims 3-5 and 16-17 are submitted not obvious variations of Claims 5 and 6 of US patent No 6,174,733 or Claims 14-22 of US patent No 6,337,214.

Moreover, Lee et al (US 5,672,475) merely teach using acridinium dye as a label, but fail to teach Applicant's claimed method.

One ordinary skilled in the art would not be motivated to combine the prior art teaching as suggested by the Examiner, because such combination would not obtain Applicant's present claimed invention of the method of sequentially binding different probes, and sequentially detecting different test materials on the same snare.

Therefore, Applicant's present claimed invention is not obvious in view of the cited references independently or in combination.

Accordingly, Applicants request withdrawal of all rejections under the judicially created doctrine of obviousness-type double patenting.

3. Response to the Rejections of Claims 1-25 Based Upon 35 U.S.C. §103(a)

Claims 1-25 stand rejected under 35 USC §103(a) as being unpatentable over Wainwright et al (US 5,876,918) in view of Bohannon (US 6,261,771). This rejection is respectfully traversed.

Claims 1, 14 and 24 are independent claims, and Claims 2-13, 15-23 and 25 are dependent claims of Claims 1, 14 and 24, respectively.

A determination under 25 U.S.C. §103 is whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made. *In re Mayne*, 104 F.3d 1339, 1341, 41 USPQ 2d 1451, 1453

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(Fed. Cir. 1997). An obviousness determination is based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and prior art; and (4) the objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966), see also *Robotic Vision Sys., Inc. v. View Eng'g Inc.*, 189 F.3d 1370 1376, 51 USPQ 2d 1948, 1953 (Fed. Cir. 1999).

In line with this standard, case law provides that "the consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art." *In re Dow Chem.*, 837 F.2d 469, 473, 5 USPQ 2d 1529, 1531 (Fed. Cir. 1988). The first requirement is that a showing of a suggestion, teaching or motivation to combine the prior art references is an "essential evidentiary component of an obviousness holding." *C.R. Bard, Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1352, 48 USPQ 2d 1225, 1232 (Fed. Cir. 1998). This showing must be clear and particular, and broad conclusory statements about the teaching of multiple references, standing alone, are not "evidence." *In re Dembiczak*, 175, F.3d 994, 1000, 50 USPQ 2d 1614, 1617. The second requirement is that the ultimate determination of obviousness must be based on a reasonable expectation of success. *In re O'Farrell*, 853 F.2d 894, 903-904, 7 USPQ 2d 1673, 1681 (Fed. Cir. 1988); see also *In re Longi*, 759 F.2d 887, 897, 225 USPQ 645, 651-52 (Fed. Cir. 1985). The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ 2d 1780, 1783-84 (Fed. Cir. 1992).

The examiner has the burden of establishing a prima facie case of obviousness. *In re Deuel*, 51 F.3d 1552, 1557, 34 USPQ 2d 1210, 1214 (Fed. Cir. 1995). The burden to rebut a rejection of obviousness does not arise until a prima facie case has been established. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ 2d 1955, 1957 (Fed. Cir. 1993). Only if the burden of the establishing prima facie case

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is met does the burden of coming forward with rebuttal argument or evidence shift to the application. In *re Deuel*, 51 F.3d 1552, 1557, 34 USPQ 2d 1210, 1214 (Fed. Cir. 1995), see also *Ex parte Obukowicz*, 27 USPQ 2d 1063, 1065 (B.P.A.I. 1992).

Applicant submits that nothing in the art of record teaches or suggests the subject matter positively recited in independent Claims 1, 14 and 24.

As recited positively in Claim 1, Applicant's claimed method for detecting multiple test materials in a test sample includes the following specific process steps in the sample sequential analysis: (a) adding a test sample into a test column having a plurality of test snares, at least one of the test snares having thereon at least two target capture materials; (c) adding a first probe to attach specifically to said bound first test material; said first probe having thereon a first chemical label; (e) detecting signals generated by said first chemical label on said test snare for determining the presence of said first test material; (f) adding a second probe to attach specifically to said bound second test material, said second probe having thereon a second chemical label; and (h) detecting signals generated by said second chemical label on said test snare for determining the presence of said second test material (emphasis added).

As recited positively in Claim 14, Applicant's claimed method for detecting multiple target nucleic acid fragments in a test sample includes following specific process steps in the sequential sample analysis: (a) adding a test sample containing single strand target nucleic acid fragments into a test column, said column having a plurality of snares, at least one of said snares being a test snare having thereon at least two single strand target capture DNA sequences; (c) adding a first single strand DNA probe to attach specifically to a probe binding site of said first target nucleic acid fragment, said first probe having thereon a first chemical label; (e) adding a first triggering solution to trigger said first chemical label; (f) detecting signals generated by said first chemical label on said test snare for determining the presence of said first target nucleic acid fragment; (h) adding a second single strand DNA probe to attach specifically to a probe binding site of said second target nucleic acid fragment, said second probe having thereon a second chemical label; (j) adding a second triggering

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solution to trigger said second chemical label; and (k) detecting signals generated by said second chemical label on said test snare for determining the presence of said second target nucleic acid fragment (emphasis added).

As recited positively in Claim 24, Applicant's claimed method for detecting multiple target nucleic acid fragments in a test sample including following specific process steps in the sample sequential analysis: (a) adding two positive control DNA sequences and a test sample containing single strand target nucleic acid fragments into a test column, said test column having at least two snares which are separate spatially one from another by an intervening air space; said test snare having thereon at least two target capture DNA sequences, (c) adding a first single strand DNA probe to attach specifically to a probe binding site of said first target nucleic acid fragment, said first probe having thereon a chemical label; (e) adding a triggering solution to trigger said chemical label; (f) detecting signals generated by said chemical label on said test snare for determining the presence of said first target nucleic acid fragment; (h) adding a second single strand DNA probe to attach specifically to a probe binding site of said second target nucleic acid fragment, said second probe having thereon said chemical label; (i) adding said triggering solution to trigger said chemical label; and (k) detecting signals generated by said chemical label on said test snare for determining the presence of said second target nucleic acid fragment (emphasis added).

As stated by the Examiner, Wainwright et al fail to teach plurality of capture materials on the same snare.

Furthermore, Wainwright et al fail to teach the steps of adding a first probe, and detecting signals on the test snare for determining the first test material; then adding a second probe, and detecting signals again on the same test snare for determining the second test material.

Moreover, Wainwright et al fail to teach the steps of adding the first triggering solution prior to detecting signals on the test snare for determining the first test material, and then adding the second triggering solution, after the first detection, prior

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to detecting signals again on the same test snare for determining the second test material.

Even further, Wainwright et al fail to teach the step of adding a sample into a test column having at least two snares which are separate spatially one from another by an intervening air space.

On the contrary, Wainwright et al teach in their method that the positive control, negative control and the test material, bound to different layers (layers 31-33, respectively), are detected at the same time, i.e., by color change on different layers at the end of the assay (Column 6, lines 26-42, and Column 8, lines 13-26). In fact, the teaching of Applicant's claimed process of adding, triggering and detecting the second probe on the same test snare after the completion of the detection of the first test material, is completely absent.

The deficiencies of Wainwright et al's reference are not overcome by Bohannon et al.

Bohannon et al teach a method of simultaneous detection of multiple test materials in a sample. More specifically, Bohannon et al teach the following:

....one or more binding sites for different target molecules are arranged in a known relationship to allow simultaneous detection of multiple nucleic acids and/or antigens in a sample. The nature of this arrangement is such that the sample may be presented to the binding sites in a single operation to provide essentially simultaneous contact of the sample with the different collector binding sites. Furthermore, the arrangement must allow the different binding sites to be distinguishable from each other. (Column 10, lines 41-50).

....Preferably, the binding site comprises a unique oligonucleotide sequence attached to a bead, and the different binding sites, i.e., different beads, are arranged along the length of a collector tube as shown in FIG. 4. (Column 10, lines 55-58)

.... Preferably, the different reporter binding site(s) are separated from

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each other by empty bead(s), i.e., lacking oligonucleotides. Thus, if a plurality of beads is used in each reporter binding site, the different reporter binding sites will have the shape of bands along the tube.a single luminometer may be moved along the length of the tube stopping at the location of each reporter binding site to monitor for light emission from that site, or multiple luminometer detectors may be positioned next to the location of each binding site as shown in FIG. 4. Alternatively,a plurality of miniature luminometers attached to the interior wall of the tube at positions corresponding to the location of each reporter binding site. (Column 11, lines 13-37)

It is apparent that Bohannon et al teach away from Applicant's claimed method of detecting multiple test materials on the same test snare using a sequential process by adding the probes at different times, triggering and detecting the signals from the labeled test materials at different times, because Bohannon et al teach to bind multiple nucleic acids and/or antigens at different and distinguishable binding sites, and detect them simultaneously.

Therefore, both the primary reference and the secondary reference teach the same approach of binding different materials at different locations, either layers, bands, or different binding sites aligned in a known order, and detecting the different materials at the same time.

Based on the opposite teachings of both references, one ordinary skilled in the art would not be motivated to combine Wainwright et al and Bohannon et al, to try to obtain Applicant's claimed method. Even if one does, in the manner suggested by the Examiner, one could only end up detecting different materials simultaneously on Bohannon et al's different binding sites which is distinguishable from each other. This is fundamentally different from Applicant's method of detecting different test materials on the same test snare, but at different times.

Therefore, Applicant maintains that Applicant's claimed invention defined by independent Claims 1, 14 and 24 is not obvious in view of prior art of the record.

With regard to Claims 2-13, 15-23 and 25, as described above, these claims

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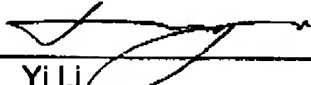
are dependent upon independent Claims 1, 14 and 24. Under the principles of 35 U.S.C. §112, 4th paragraph, all of the limitations of each independent claim are recited in its respective dependent claims. As described above, independent Claims 1, 14 and 24 are not anticipated by the prior art of record, as such Claims 2-13, 15-23 and 25 are submitted as being allowable over the art of record.

Accordingly, Applicant respectfully requests withdrawal of the rejection of Claims 1-25 based upon 35 U.S.C. §103(a).

It is respectfully submitted that Claims 1-25, the pending claims, are now in condition for allowance and such action is respectfully requested.

Applicant's Agent respectfully requests direct telephone communication from the Examiner with a view toward any further action deemed necessary to place the application in final condition for allowance.

1/29/2005
Date of Signature

By: 
YI LI
Registration No. 44,211
Agent of the Applicant

Address correspondence to:

CUSPA Technology Law Associates
11820 SW 107 Avenue
Miami, FL 33176
Phone: (786) 242-9349
Fax: (786) 242-9349